

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13265



7 - PROCEDURES

000001

Patient: [REDACTED]

Account Number: [REDACTED]

Surgeon: [REDACTED] M.D.

1st Assistant: [REDACTED], M.D.

Dictated By: [REDACTED] M.D.

2nd Assistant: [REDACTED]

Date of Operation: 10/19/98

Patient Location: [REDACTED]

Patient Type: I

Pre-Operative Diagnoses:

1. Left adnexal mass measuring 16 x 9 x 9 cm.
2. Mucinous cystadenoma based on frozen section.

Post-Operative Diagnoses:

1. Left adnexal mass measuring 16 x 9 x 9 cm.
2. Mucinous cystadenoma based on frozen section.

Operation:

1. Exploratory laparotomy.
2. Left salpingo-oophorectomy.

Anesthesia: Epidural.

Blood loss: The estimated blood loss was 50 cc.

Fluids: 2000 cc crystalloid.

Operative Findings: Approximately 20 x 9 cm left ovarian mass. The surface was noted to be smooth. The right ovary was noted to be normal with a small 0.5 to 1 mm cyst which was ruptured. Clear fluid was noted on rupture of that cyst. The upper abdomen including liver and diaphragm was noted to be within normal limits. The pelvis otherwise was noted to be within normal limits. There is no pelvic fluid noted. The appendix was also visualized and noted to be within normal limits.

Operative Indications: [REDACTED] is a 40-year-old, gravida 2, para 2 who presented to the Emergency Room approximately a week and a half prior to admission with complaint of abdominal pressure. Ultrasound was obtained and findings are as noted above. The patient also complained of some abdominal pain. She otherwise had normal bowel and bladder function.

Preoperative work up included CBC which was normal, chest x-ray which was noted to be normal. Liver function tests were ordered. Results were not obtained prior to procedure. A Pap smear was also obtained and noted to be normal.

Procedure: The patient was brought to the Operating Room where her anesthesia was found to be adequate. She was then prepped and draped in the normal sterile fashion after being placed in the supine position. A vertical skin incision was then made with a scalpel and carried through to the underlying layer of fascia. The fascia was then nicked and the fascial incision was extended superiorly and inferiorly. The rectus muscles were

O P E R A T I V E R E P O R T

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Patient: [REDACTED]

Account Number: [REDACTED]

Dictated By: [REDACTED] M.D.

Date of Operation: 10/19/98

Patient Location: [REDACTED]

Patient Type: [REDACTED]

when separated in the midline and the peritoneum was identified and entered sharply. The peritoneal incision was then extended superiorly and inferiorly with good visualization of the bladder. Upon entering the peritoneal cavity, the adnexal mass was visualized. Pelvis washings were obtained and sent. The mass was then elevated above the skin.

The broad ligament posterior sheath was then opened with good visualization of the infundibulopelvic ligament and the round ligaments. These structures were kept intact as the posterior sheath was opened. The IP (infundibulopelvic) ligament was then isolated. The ureter was visualized and a window was made using a right angle in the posterior sheath and the broad ligament below the infundibulopelvic ligament. The IP ligament was then doubly clamped with two right angles and cut. The IP pedicle was then suture ligated using #0 Vicryl suture followed by suture ligation with the same size and type of suture. Good hemostasis was noted at this pedicle. The utero-ovarian vessels were then isolated by using sharp dissection, again maintaining integrity of the round ligament. Two Heaney clamps were then placed across the utero-ovarian ligament. The specimen was then removed and the utero-ovarian ligament was suture ligated with #2-0 Vicryl stitches. Good hemostasis was noted at this pedicle. The results of the frozen section were then awaited. The results are as noted above (mucinous cystadenoma, benign looking, an area of squamous stratification. Per the pathologist, no further frozen sections were necessary. At this point, the pelvis was then irrigated. All pedicles were re-examined and noted to be hemostatic. The fascia, muscle and peritoneum were then reapproximated using #0 PDS in a running fashion with a mass closure. Good hemostasis was noted. A #2-0 Vicryl was used to reapproximate the subcutaneous tissue. The skin was then closed with staples.

The patient tolerated the procedure well. All counts were correct times two. She was transferred to the Recovery Room in stable condition.

[REDACTED] M.D. for [REDACTED] M.D.

DD: 10/20/98

DT: 10/22/98 [REDACTED]

10/29/98

OPERATIVE REPORT

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COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR EXH. E19 of I

SURGICAL PATHOLOGY

Collected: 10/19/98

Accession:

Physician:

PROCEDURE

Exploratory laparotomy and LSO.

HISTORY

This G2P2 patient presents with a left adnexal mass.

GROSS

"Left adnexal mass." A 1570 gm, 17 x 16 x 9 cm cystic mass. The unilocular cyst has a smooth inner and outer lining. There are no papillary excrescences noted. The cyst is filled with clear yellowish fluid. The lesion is sampled for frozen section evaluation. Frozen section control, all processed for microscopy - 1 cassette. Additional material sampled for microscopy - 8 sections.

FROZEN SECTION DIAGNOSIS

ADNEXA (LEFT): GROSSLY BENIGN CYSTADENOMA WITH FOCI OF STRATIFIED SQUAMOUS EPITHELIUM.

M.D.

M.D.

MICROSCOPIC

The ovary is largely replaced by a benign cystic mass. A portion of the cyst lining is benign mucinous epithelium. The predominant lining cell is a transitional cell, often multilayered. In addition, transitional cell nests are scattered throughout the stroma. Therefore, this is a cystic Brenner tumor and mucinous cystadenoma. These two often coexist. There is no evidence of malignancy. The fallopian tube is unremarkable.

DIAGNOSIS

OVARY (LEFT): BENIGN CYSTIC BRENNER TUMOR AND MUCINOUS CYSTADENOMA.

FALLOPIAN TUBE (LEFT): NO PATHOLOGIC DIAGNOSIS.

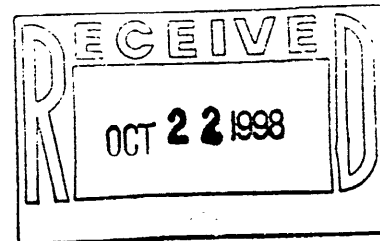
M.D.

(Electronic Signature)

10/21/98

11.5

put on chart



COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR EXH. E-20 of 1

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ENZYMES

10/20/98
0820SGOT
SGPT18
12REF RANGE
8-40 IU/L
9-52 IU/L

CHEMISTRY - MISCELLANEOUS

10/07/98
1225

HCG-URINE

NEGATIVE

REF RANGE

BLOOD COUNTS

10/20/98 10/14/98
0730 1530HGB
HCT
RBC
MCV
MCHC
RDW
WBC
PLT12.3 14.3
35.2L 41.8
3.95L 4.66
89 90
35.1 34.2
12.4 11.9
5.0 5.5
188 265REF RANGE
12.0-16.0 GM/DL
36.0-48.0 %
4.20-5.40 M/UL
82-100 FL
32.0-36.0 %
11.0-14.0 %
4.0-10.0 K/UL
140-450 K/UL

URINALYSIS

20OCT98 07OCT98
1445 1205COLLECTION PROC
COLOR
APPEARANCE
SPECIFIC GRAVIT
PH
PROTEIN
GLUCOSE
KETONES
BILIRUBIN
BLOOD
UROBILINOGENROUTINE ROUTINE
YELLOW STRAW
HAZY* CLEAR
1.012 1.006
5.0 6.5
NEGATIVE NEGATIVE
NEGATIVE NEGATIVE
NEGATIVE NEGATIVE
NEGATIVE NEGATIVE
NEGATIVE NEGATIVE
0.2 0.2REF RANGE
YELLOW
CLEAR
1.005-1.030
5.0-7.0
NEGATIVE
NEGATIVE
NEGATIVE
NEGATIVE
NEGATIVE
0.2-1.0

L=Low, *-Abnormal

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FILE IN PATIENT CHART
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Continued...RESULTS THROUGH
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02/01-02/99 RLR EXH. E-13 of I

Admit: 10/19/98
Room

REFERENCE LABORATORIES

Test(s) Performed At
10/07/98

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FILE IN PATIENT CHART
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Continued...

RESULTS THROUGH
21OCT98 0007

COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR EXH. E-15 of I

Admit: 10/19/98
Room: [REDACTED]

CYTOLOGY

Collected: 10/09/98
Accession: [REDACTED]

HISTORY

Date Received: 10/10/98
LMP? 09-28-98
Pregnant? NO
BCPs? NO
Estrogen?
Hysterectomy?
Comment: HX OF DYSPLASIA AND LASER

SOURCE

Cervical Smear with EC Brush

ADEQUACY

Satisfactory. Endocervical component present.

INTERPRETATION

Estrogen effect consistent with age and history.

Within Normal Epithelial Limits.

COMMENT

Blood is present.

Staff Cytotechnologist
(Electronic Signature)
10/12/98 [REDACTED]

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FILE IN PATIENT CHART
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Continued...

RESULTS THROUGH
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COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR EXH. E-16 of I *rer*

Admit: 10/19/98
Room: [REDACTED]

NON-GYN CYTOLOGY

Collected: 10/19/98
Received: 10/19/98
Accession: [REDACTED]

HISTORY

Left adnexal mass - benign cystadenoma.

SOURCE

Intraoperative Peritoneal Wash

SPECIMEN

70 cc bloody fluid.
4 slides prepared.
1 cell block.

ADEQUACY

Satisfactory for interpretation.

INTERPRETATION

Mesothelium.
Fragments of skeletal muscle and adipose tissue.
Negative for malignant cells.

[REDACTED]
[REDACTED]
(Electronic Signature)
10/20/98 [REDACTED]

M.D.

Reference Laboratories

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**FILE IN PATIENT CHART
- REPLACE DAILY -**

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End of Report

**RESULTS THROUGH
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COMPLAINT/INJURY F/U DET-0789
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